IN THE DRAWINGS

Please insert Figs. 1-3.

REMARKS/ARGUMENTS

Claims 1-15 are active. Claims 16-24 have been withdrawn from consideration.

Election/Restriction

Group I, Claims 1-15, directed to particular strains FERM BP 08462, 08463, 08464 and 08465 and compositions and methods involving these strains was previously elected. The Applicants respectfully request that upon an indication of allowability for the elected subject matter that nonelected claims which depend from or otherwise include all the limitations of an allowable claim be rejoined and also allowed.

Drawings/Specification

The Applicants respectfully request entry of Figs. 1-3 which while omitted from the original filing are described on pages 3-4 of the specification as filed. These figures do not appear to be essential for description of the present claims since these claims have not been rejected for lack of adequate support in the disclosure. Accordingly, the Applicants respectfully request that pursuant to 37 C.F.R. 1.18(c) that the Examiner require the addition of these figures to the disclosure and approve the entry of the attached figures.

Rejection—35 U.S.C. 112, first paragraph (Deposit)

Claims 1-15 were rejected under 35 U.S.C. 112, first paragraph as lacking adequate description or enablement by not complying with the deposit rules. The strains in question are described on page 7 of the specification. As required by the Deposit Rules the Applicants state:

> *Pseudomonas* strains FERM BP-08462, FERM BP-08463, FERM BP-08464, and FERM BP-08465 were deposited under the terms of the Budapest Treaty. As required by 37 C.F.R. 1.808, subject to the one exception permitted by 37

> C.F.R. 1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent. See MPEP 2410.01.

Accordingly, the Applicants respectfully request that this rejection now be withdrawn.

Rejection—35 U.S.C. §101

Claims 1-10 were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. This rejection is moot in view of the amendment of these claims.

Rejection—35 U.S.C. §102

Claims 1-15 were rejected under 35 U.S.C. 102(a) as being anticipated by Hosokawa et al., Environ. Microbiol. 4:03-712. This rejection is moot in view of the attached Declaration which indicates that Hosokawa et al. is the work of the present inventors.

Rejection—35 U.S.C. §102 or §103

Claims 1-15 were rejected under 35 U.S.C. 102(b)/103(a) as being unpatentable over Ramos-Gonzales et al., Appl. Environ. Microbiol. 67:4338 and/or Huertas et al. ("Ramos-Gonzales et al."), Environ. Sci. Technol. 34:3395. The Applicants traverse these grounds of rejection because the present claims are limited to particular deposited strains of *Pseudomonas putida*, namely FERM BP-08462, FERM BP-08463, FERM BP-08464, which contain specific genetic mutations to *Pseudomonas putida* strains which are not disclosed or suggested by the cited prior art. These mutations are described on pages 6-7 of the specification (see bridging paragraph) and include an *Str* mutant (FERM BP-08463), *Gen* mutant (FERM BP-08463), *Rif* mutant (FERM BP-08463) and an *Str* and *Gen* double mutant (FERM BP-08464). The cited prior art does not disclose or suggest these specific mutants.

Anticipation. The anticipation-basis for this rejection asserts that the deposited strains are identical to the prior art strains, but does not cite prior art teaching the particular mutations in the deposited strains.

> "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is ***necessarily*** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art", Continental Can Co. USA v. Monsanto Co., 20 USPQ2d (Fed. Cir. 1991), MPEP 2131.01(III).

The claimed deposited strains are not anticipated because one of ordinary skill in the art would understand that the genetic mutations of the deposited strains are not ***necessarily*** present in the prior art strains. It is not reasonable to assert that strains isolated from separate sources are genetically identical due to known intraspecies genetic variation. The prior art strains DOT-T1E and MTB6 strains were separately isolated from nature and thus would not have exactly the same genetic characteristics as the deposited strains which were derived from a different isolate: KH 146-2 (see specification, page 8, lines 20-25). One with skill in the art would understand that due to genetic variation within a species that the isolation of genetically identical strains from different sources is astronomically small. Accordingly, the anticipation rejection is improper, since it does not set forth a reasonable basis for concluding that the deposited strains are identical to the DOT-T1E and MTB6 strains. The Applicants also respectfully submit that one with skill in the art would understand that the claimed deposited strains are genetically and functionally distinct from the prior art strains for the following reasons.

(1) Ramos et al., J. Bacteriol. 177: 3911 (attached) describes that *P. putida* DOT-T1, a parent strain of DOT-T1E was isolated via enrichment culture from nature. Enrichment

culture is a method for obtaining a potentially tolerant strain which exist with low frequency in the nature, so that is basically completely different from a production of mutant strain with mutation agent etc. Therefore, it is difficult to consider that DOT-T1 and its derivative DOT-T1E have "mutation" in genes of ribosomal protein S12 and RNA polymerase like the present microorganism.

(2) Ramos-Gonzalez et al. (2001), discloses that pre-exposure of DOT-T1E to 4HBA will result in increase in apparent tolerance to 4HBA. This means is called "adaptation", and is conventionally used. Here the change occurred is known to be a physiological change, not genetic one. Specifically, the obtained characteristics will disappear if cultivated again under the original condition. That is why the reference as well as the document mentioned in the above (1) never use the term "mutation".

(3) Maria-Jose Huertas et al. discloses an isolation of *P. putida* MTB6 from nature with sudden toluene shock. However, this is one of the means to isolate tolerant strain existing with low frequency in the nature, and thus it is impossible to consider that the mutations in the deposited strains were generated in MTB6.

(4) While Ramos-Gonzalez et al. (2001) adopts a means called adaptation, which is completely different from the present invention, the microorganism obtained shows similar function with that of the present invention; i.e. being tolerant to 4HBA. But it is natural that microorganisms obtained by different means genetically differ with each other even if they happened to have similar function. For example, N. Tamehiro et al. Appl. *Environ. Microbiol.* Vol.69, No.11, (2003) p.6412-6417 (attached) discloses that productivity of salinomycin was improved by introducing mutation into genes of ribosomal protein S12 and RNA polymerase of highly salinomycin-productive strain of *Streptmyces albus* (SAM-X). This document shows that even if genes of S12 protein and RNA polymerase of SAM-X are wild-type, these genes have the function of highly producing salinomycin like the mutant

strain. In other words, it is clear that highly salinomycin-productive strain SAM-X possesses many mutations to increase salinomycin productivity, but these mutations are apparently different from S12 mutation and RNA polymerase mutation which also increase salinomycin productivity.

Obviousness. The claimed deposited strains were alternatively rejected as being functional equivalents of the prior art strains on the grounds that they degrade toxic compounds and the prior art strains degrade toxic compounds. However, the deposited strains inherently also contain structural features, namely the specific gene mutations described on pages 6-7 of the specification, which are not disclosed or suggested by the prior art. The rejection does not establish that these genetic characteristics are necessarily present in the prior art strains and one with ordinary skill in the art would not assume that they are due to the specificity of the mutations and intraspecies genetic variability. Therefore, this ground of rejection should be withdrawn, because the prior art does not disclose all the elements of the claimed invention, namely strains having the particular structural genetic characteristics of the claimed and deposited strains.

The Applicants also traverse an obviousness rejection based on the premise that the genus of *Pseudomonas putida* strains renders the particular species (i.e., the deposited strains) obvious. Table 2 on page 15 of the specification, clearly distinguishes the functional properties of the deposited mutant strains (strains 3, 12 and 17 in Table 2 correspond to claimed/deposited strains, strain 55 is not shown in Table 2 but some of its distinguishing characteristics are described on page 19). from the *Pseudomonas putida* wild-type strain from which they were derived. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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